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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,337	02/27/2002	Henry Yue	PF-0742 USN	2453
22428	7590	09/09/2004	EXAMINER	
FOLEY AND LARDNER SUITE 500 3000 K STREET NW WASHINGTON, DC 20007			SAIDHA, TEKCHAND	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 09/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/070,337	Applicant(s) YUE ET AL.	
	Examiner Tekchand Saidha	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 1,2,10 and 13-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-9 & 11-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's election with traverse of Group 16, claims 3-9 & 11-12, filed July 15, 2004, is acknowledged. The traversal is on the grounds that the search and examination of at least groups 16 and 5 [polynucleotide of SEQ IDNO: 16 and the encoded polypeptide of SEQ ID NO: 5] is not unduly burdensome. According to M.P.E.P section 803 "if a search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to independent and distinct inventions.

This is not found persuasive because depending upon the restricted group (16 or 5) being examined, additional classes/subclasses have to be searched. For example, Group 16 claims, drawn to nucleic acid encoding a polypeptide, vector and host cell, will involve searching for class 536 & subclass 23.1 for DNA encoding the enzyme, class 435 & subclasses 252.3 & 320.1 for host cell and vector; and Group 5 claims, drawn to polypeptide composition, will involve searching for additional class 424 subclass 94.5. Further, Group 16 will further involve an oligonucleotide search for 60 [contiguous] nucleotides [SEQ ID NO: 16] as compared to polypeptide fragments of SEQ ID NO: 5 for Group 5. This additional searching as explained above would therefore involve undue burden to the Examiner.

The traversal is further on the ground(s) that “when the U.S. Patent and Trademark Office considers international applications ... during the national stage as a Designated or Elected Office under 35 U.S.C. 371, PCT Rule 13.1 and 13.2 will be followed when considering unity of invention of claims of different categories without regard to the practice in national applications filed under 35 U.S.C. 111. ...

In applying PCT Rule 13.2 ... to national stage applications under 35 U.S.C. 371, examiners should consider for unity of invention of all the claims to different categories of invention in the application and permit retention in the same application for searching ...claims to the categories which meet the requirements of PCT Rule 13.2.

Applicant cites Example 17, Part 2 of Annex B to the Administrative Instructions Under the PCT, which states:

Example 17

Claim 1: Protein X.

Claim 2: DNA sequence encoding protein X.

Expression of the DNA sequence in a host results in the production of a protein which is determined by the DNA sequence. The protein and the DNA sequence exhibit corresponding special technical features. Unity between claims 1 and 2 is accepted.

Applicant argues the examiner should withdraw the lack of unity requirement with respect to claims of Groups 5, drawn to the special technical feature of a polypeptide, and co-examine the claims of Group 16. Applicants further argue as per PCT Rule 13.2 that Groups 5 and 16 share the same corresponding special technical feature in the protein of Group 5 and the DNA

which encodes the protein of Group 5 is the DNA of Group 16 and, as such, should be rejoined and examined in the present application.

According to PCT Rule 13.2, unity of invention exists only when there is a shared same or corresponding special technical feature among the claimed inventions. Furthermore, according to PCT Rule 13.2, unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art.

The inventions of Groups 16 and 5 do not have unity of invention because the technical feature of Group 16 is not a contribution over the prior art. Claim 3 is drawn not only to any polynucleotide encoding a polypeptide having 90% identity to SEQ ID NO: 5 or a biological active fragment thereof, or an immunogenic fragment with no activity, size or homology limitation, which therefore, reads upon any polynucleotide, for example, SEQ ID NO: 4 of USP 5543499, wherein nucleotides 1518-1399 are identical to Applicants' SEQ ID NO: 16, nucleotides 836-955. That is a match of 119 contiguous nucleotides, and also reads on 60 contiguous nucleotides of claim 12. As a consequence, the cited prior art defines that the technical feature so claimed as not a contribution over the cited prior art. Therefore, Unity of Invention is lacking.

The lack of unity determination is still deemed proper but is not made FINAL because of the newly introduced prior art.

2. **Claims 3-9 and 11-12** [SEQ ID NO : 16 encoding SEQ ID NO : 5] are under consideration in this Office Action.

3. Claims 1-2, 10 & 13-28 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

4. **Objection**

Claims 3-9 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 3-9 depend directly or indirectly from non-elected claims. Placing the claims in proper dependent form will overcome this objection.

5. The Examiner notes that if product claims are found allowable, then the process claims, which are directed to processes of making or using the patentable product [i.e. the DNA sequence of SEQ ID NO : 16, covering the same scope as of the allowable product)], respectively, previously withdrawn from consideration as a result of a restriction requirement, would be rejoined pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86; see also M.P.E.P. § 821.04, *In re Ochiai*, and *In re Brouwer*). Since process claims would be rejoined and fully examined for patentability under 37 C.F.R. § 1.104, Applicants are instructed to amend said claims as deemed necessary according to rejections made against the elected claims.

6. **Written Description**

Claims 3, 8-9 & 11-12 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims are directed to a genus of DNA (or polynucleotide) molecules wherein DNA sequence is 90% identical to SEQ ID NO : 16 or encode a polypeptide sequence which is 90% identical to SEQ ID NO: 5 with no defined function.

The specification does not contain any disclosure or description of the structure and function of all DNA sequences that are 90% identical to SEQ ID NO : 16, or wherein such a DNA would likely encode a polypeptide(s) having 90% similarity to SEQ ID NO: 5 or a biological or immunological fragment thereof. Further, the specification as filed does not describe specific assays to measure the various polypeptide sequences having the 'protein phosphatase protein kinase activity' or which is so evident, as none is described. It is also not known what the substrates are. The genus of DNAs that comprise these above DNA molecules is a large variable genus with the potentiality of encoding many different proteins. Further, using these DNAs for making a transgenic organism(s) [organism = living plant, animal including human etc.], remain not described. Therefore, many functionally unrelated DNAs are encompassed within the scope of these claims, including partial DNA sequences. The specification discloses the DNA sequence of SEQ ID No. 16 encoding protein

Art Unit: 1652

phosphatase protein kinase of SEQ ID NO: 5 of the claimed genus which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. [Other sequences of SEQ ID NO: 12-15 & 17-22 are disclosed but these sequences are structurally distinct and may or may not encode a common activity]. Further it is impossible to make 60 contiguous nucleotide fragments of sequences not described. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

7. ***Enablement Rejection***

Claims 3, 8-9 & 11-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polynucleotide sequence of SEQ ID NO: 16, encoding a protein phosphates (or) protein kinase polypeptide sequence of SEQ ID NO: 5, does not reasonably provide enablement for any polynucleotide having 90% identity to SEQ ID NO: 16 or that encoding a protein which is 90% identical to SEQ ID NO: 5. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The scope of the claims does not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polynucleotides broadly encompassed by the claims. Since the amino acid

Art Unit: 1652

sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to the nucleotide [SEQ ID NO: 16] and encoded amino acid sequence of SEQ ID NO : 5.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass all modifications of DNA of SEQ ID NO: 16 or 5 by 10%, because the specification does not establish: (A) regions of the protein structure which may be modified without effecting Protein kinase or protein phosphatase

Art Unit: 1652

activity; (B) the general tolerance of Protein kinase or protein phosphatase to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any Protein kinase or protein phosphatase residues with an expectation of obtaining the desired enzymatic or biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

This is further supported in the work of Seffernick et al. [J. Bacteriol. Apr. 2001, p. 2405-2410] where melamine Deaminase and Atrazine chlorohydrolase each consists of 475 amino acids, are 98% identical and are yet functionally different. Thus there is high unpredictability associated with respect to modification(s) of the sequence of SEQ ID NO : 16 or 5 unless guidance is provided in establishing (A) – (D) as discussed above.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims. Further it is impossible to make 60 contiguous nucleotide fragments of sequences not described. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of exact nature Protein kinase or protein phosphatase encoding DNA (or polynucleotide) having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is

Art Unit: 1652

unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

8. Claims 3-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3-9 recite the phrase "biologically active fragment" in the base claim 1. The claims are indefinite because it is unclear what activity is considered biological activity. Is it enzymatic or immunological ? Using a definite enzymatic activity "either phosphatase or kinase" and for which there is evidence in the specification may overcome this rejection.

Claims 3-9 are included in this rejection for failing to correct the defect present in the base claim.

9. Claims 3-9 & 11-12 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility.

Applicants disclose a nucleic acid sequence (SEQ ID NO: 16) encoding the amino acid sequence of SEQ ID NO: 5. Based on reasonable sequence homology, the polypeptide of SEQ ID NO: 5 is sought to be a polypeptide having protein phosphatase protein kinase [PPHK] activity which is a generic asserted utility. Polypeptide(s) having PPHK activity belong to no known family of enzymes or proteins involved in any specific biological process(es). It is nearly impossible from sequence homology alone to attribute a specific and

Art Unit: 1652

substantial function for the protein. There appears to be two activities – ‘protein phosphatase and protein kinase’. Even accepting the plausible utility of being a polypeptide having PPHK activity, one of ordinary skill in the art would not know which one of two PPHK are associated with the polypeptide. The specification does not disclose a specific function of the polypeptides of SEQ ID NO: 5, its relationship to any disease, or any specific real world use. The specification describes generic functions for the protein, nucleic acid, and antibodies. The utility of the variant nucleic acid is said to be associated with encoding defective polypeptides, wherein the variants are associated with disease state, such as the diseases listed in the instant specification (for example, developmental or immune disorder, or for treating a variety of cancers, see page 36-37). It appears that the main utility of the polypeptide and nucleic acid is to carry out further research to identify the biological function and possible diseases associated with said function. Substantial utility defines a real world use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a real world context of use are not substantial utility. Thus, the claimed invention has no specific or substantial asserted utility.

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 1652

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3, 6-9 & 12 are rejected under 102(b) as being anticipated by Meyers et al. [USP 5543499, 8.6.1996].

Claim 3 is drawn to any polynucleotide encoding a polypeptide having 90% identity to SEQ ID NO: 5 or a biological active fragment thereof, or an immunogenic fragment with no activity, size or homology limitation, which therefore, reads upon any polynucleotide, for example, SEQ ID NO: 4 of USP 5543499, wherein nucleotides 1518-1399 of SEQ ID NO: 4 are identical to Applicants' SEQ ID NO: 16, nucleotides 836-955. That is a match of 119 contiguous nucleotides, and also reads on 60 [contiguous] nucleotides of claim 12. Vector, host cell, promoter sequence and transgenic organism, the limitation of claims 6-9 are also taught by the reference. The reference therefore anticipates the claims.

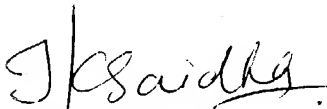
12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tekchand Saidha whose telephone number is (571) 272 0940. The examiner can normally be reached on 8.30 am - 5.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (571)

272 0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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